TMA DoD Pharmacoeconomic Center
Fort Sam Houston, TX

MTF Quarterly Webcast
June 14, 2012

Introduction

- Greetings from the PEC
- Purpose of the Quarterly MTF Webcast
- DCO Ground Rules
  - Type questions into the DCO system
  - Put on mute, not on hold
  - Contingency plan if DCO system stops working

Outline

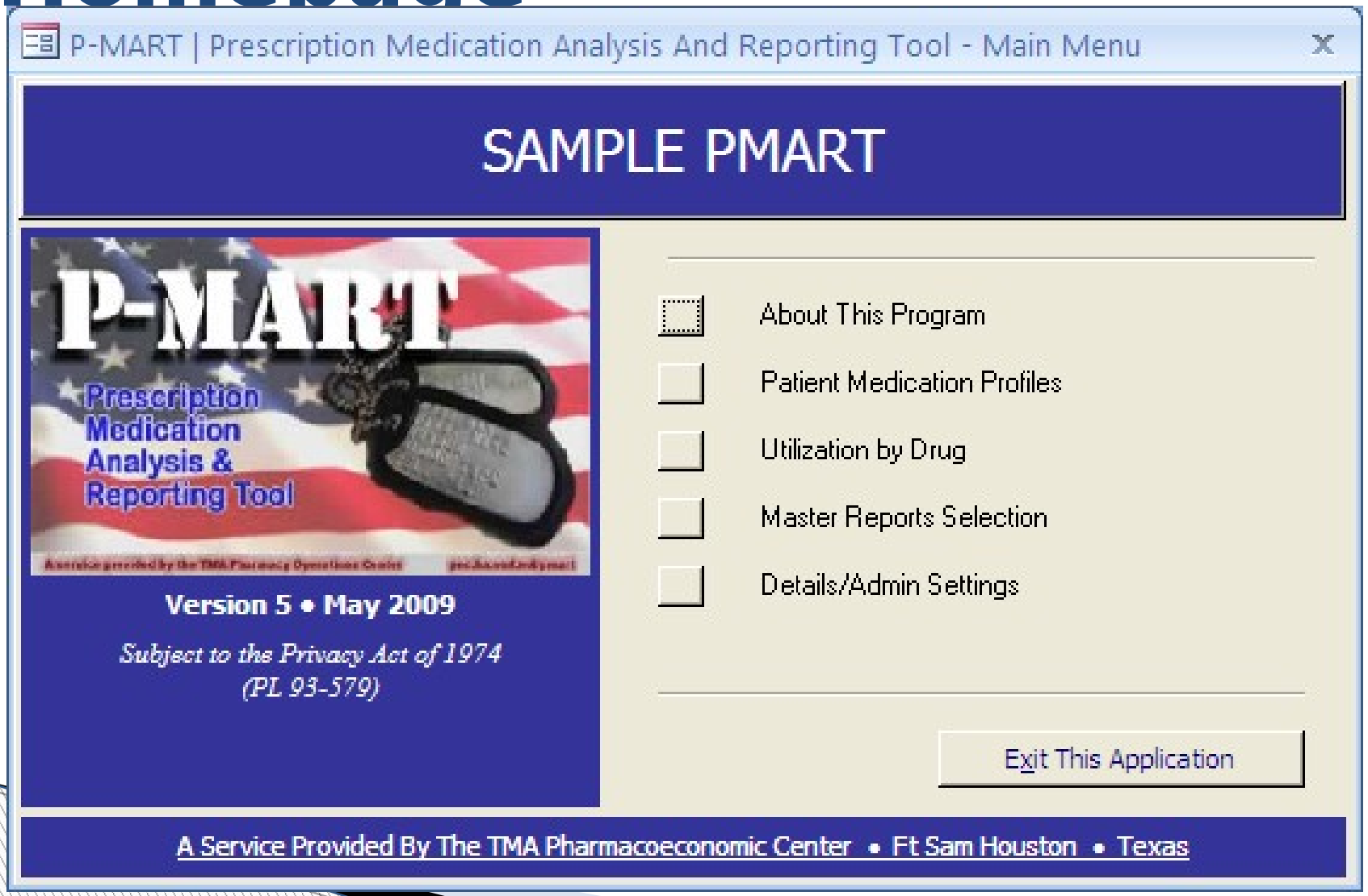
- MTF Corner- PMART (Mr. Morales)
- Review of February 2012 P&T Committee Meeting (Dr Meade)
- Overview of May 2012 P&T Committee Meeting (Dr Meade)
- Questions

Prescription Medication Analysis & Reporting Tool (PMART)

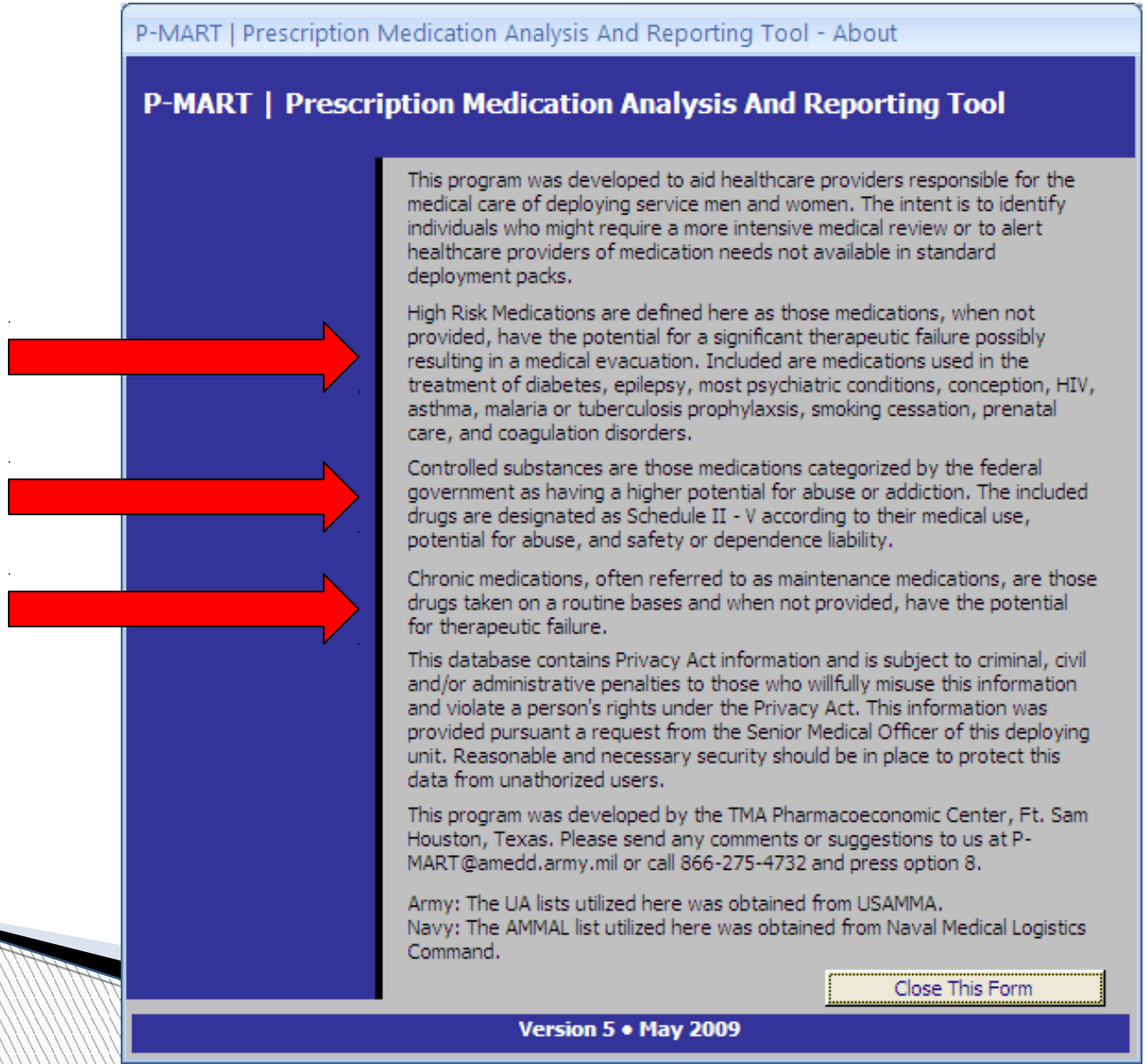
Report Tool Summary

- Medication profile snapshot for deploying SMs
  - Pre-deployment medication screening
  - Identification of high-risk SMs
  - Identification of SMs who require CENTCOM waiver
- Menu-driven, Microsoft Access database with look-up features and reports
- Pharmacy Data Transaction Service (PDTS) is data source
  - All DoD Pharmacy points of service
- Report turn-around 24 – 72 hours

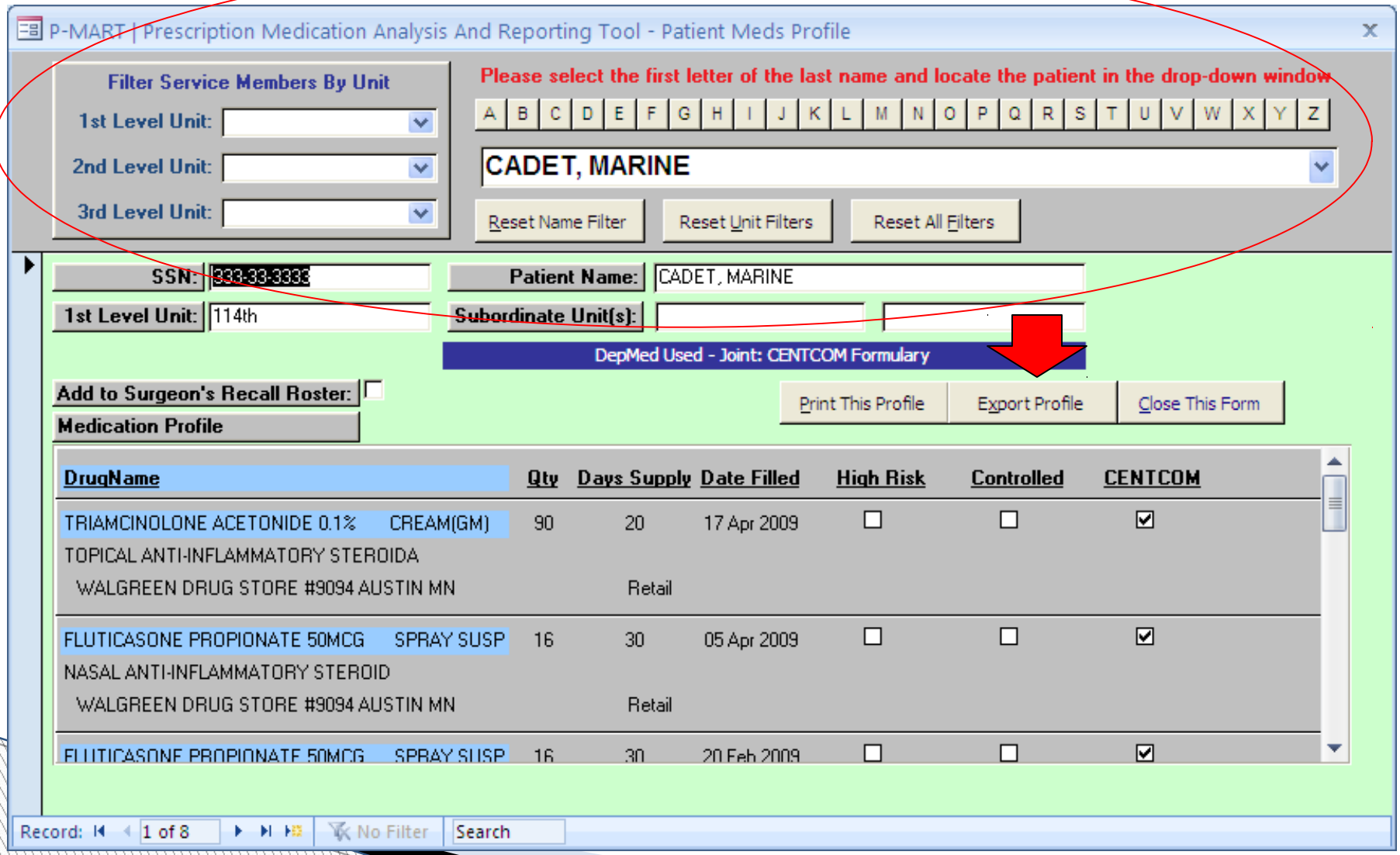
Deployment PMART Homepage


P-MART | Prescription Medication Analysis And Reporting Tool - Main Menu
SAMPLE PMART
P-MART
Prescription Medication Analysis & Reporting Tool
Version 5 • May 2009
Subject to the Privacy Act of 1974 (PL 93-579)
About This Program
Patient Medication Profiles
Utilization by Drug
Master Reports Selection
Details/Admin Settings
Exit This Application
A Service Provided By The TMA Pharmacoeconomic Center • Ft Sam Houston • Texas

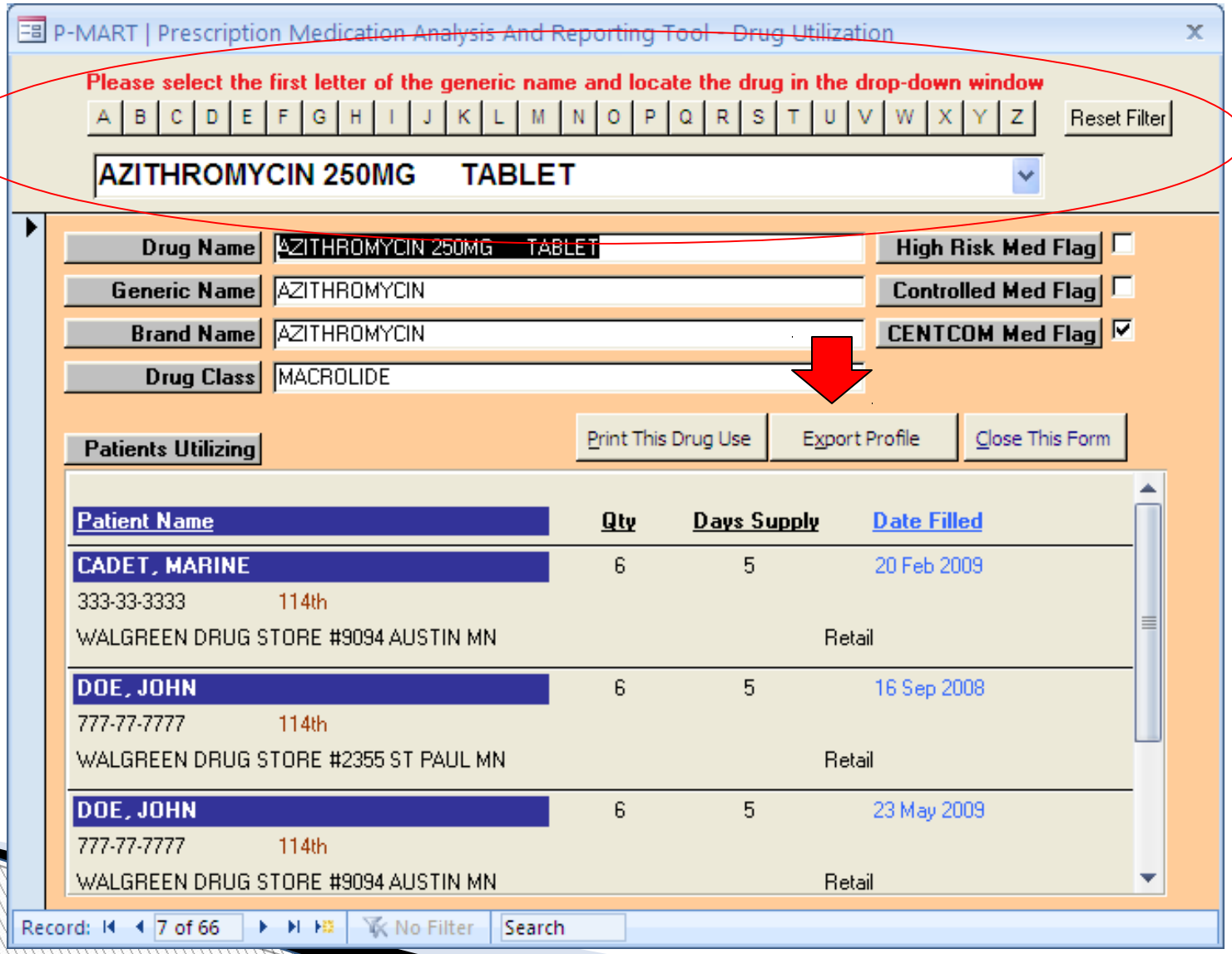
About This Program Button


P-MART | Prescription Medication Analysis And Reporting Tool - About
P-MART | Prescription Medication Analysis And Reporting Tool
This program was developed to aid healthcare providers responsible for the medical care of deploying service men and women. The intent is to identify individuals who might require a more intensive medical review or to alert healthcare providers of medication needs not available in standard deployment packs.
High Risk Medications are defined here as those medications, when not provided, have the potential for a significant therapeutic failure possibly resulting in a medical evacuation. Included are medications used in the treatment of diabetes, epilepsy, most psychiatric conditions, conception, HIV, asthma, malaria or tuberculosis prophylaxsis, smoking cessation, prenatal care, and coagulation disorders.
Controlled substances are those medications categorized by the federal government as having a higher potential for abuse or addiction. The included drugs are designated as Schedule II - V according to their medical use, potential for abuse, and safety or dependence liability.
Chronic medications, often referred to as maintenance medications, are those drugs taken on a routine bases and when not provided, have the potential for therapeutic failure.
This database contains Privacy Act information and is subject to criminal, civil and/or administrative penalties to those who willfully misuse this information and violate a person's rights under the Privacy Act. This information was provided pursuant a request from the Senior Medical Officer of this deploying unit. Reasonable and necessary security should be in place to protect this data from unathorized users.
This program was developed by the TMA Pharmacoeconomic Center, Ft. Sam Houston, Texas. Please send any comments or suggestions to us at P-MART@amedd.army.mil or call 866-275-4732 and press option 8.
Army: The UA lists utilized here was obtained from USAMMA.
Navy: The AMMAL list utilized here was obtained from Naval Medical Logistics Command.
Close This Form
Version 5 • May 2009

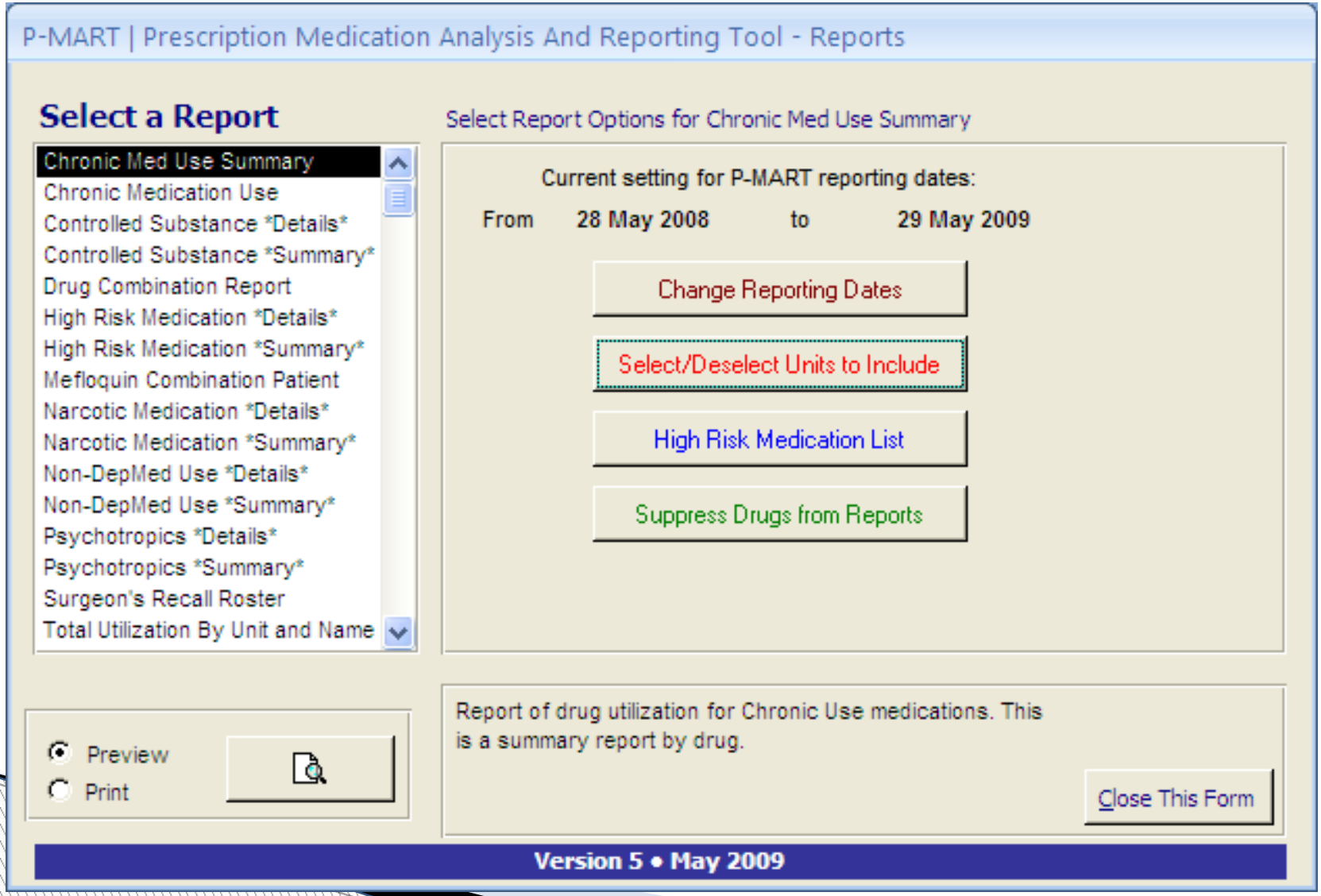
Patient Medication Profiles Button



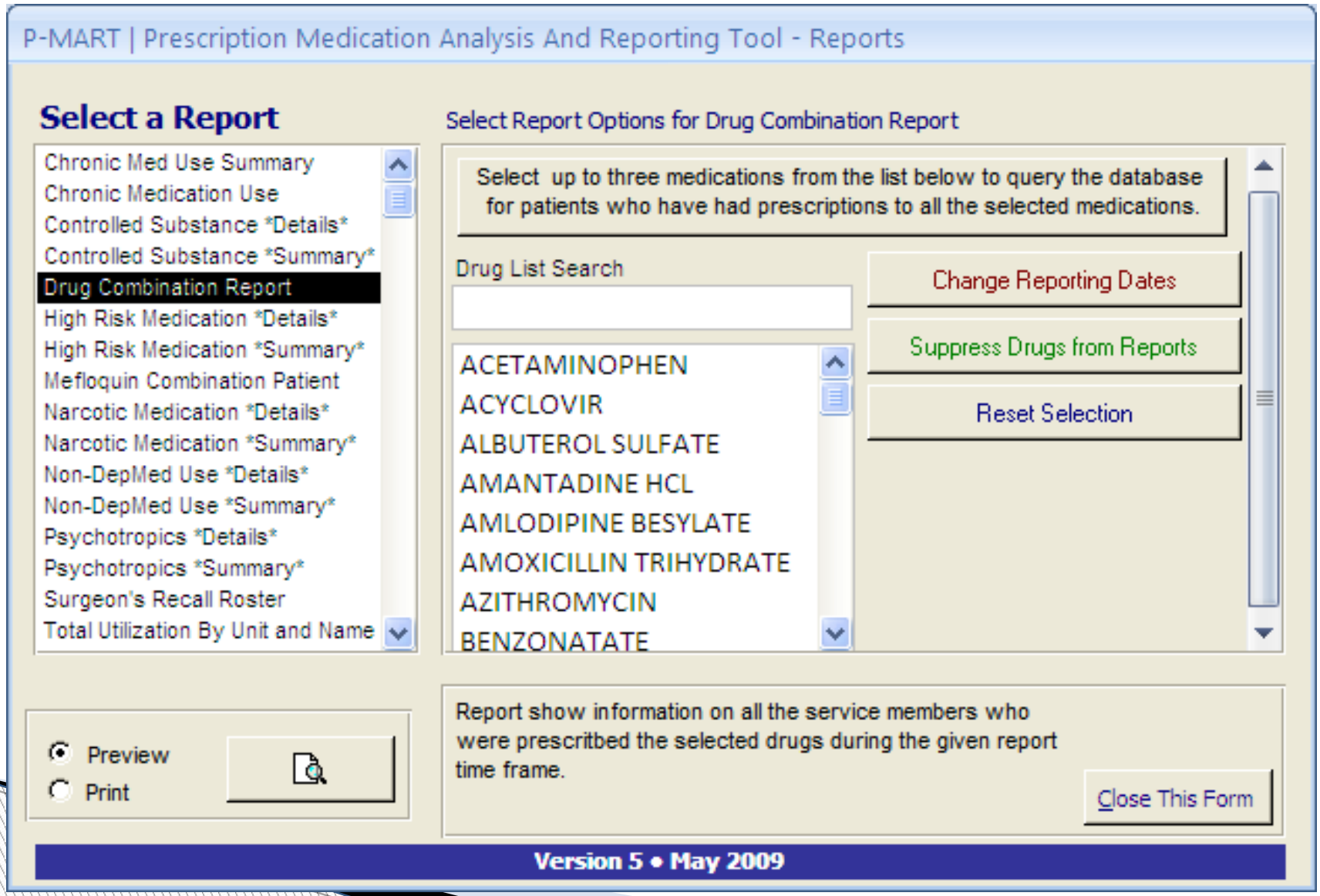
Utilization by Drug Button



Master Reports Selection Button


P-MART | Prescription Medication Analysis And Reporting Tool - Reports
Select a Report
Chronic Med Use Summary
Chronic Medication Use
Controlled Substance *Details*
Controlled Substance *Summary*
Drug Combination Report
High Risk Medication *Details*
High Risk Medication *Summary*
Mefloquin Combination Patient
Narcotic Medication *Details*
Narcotic Medication *Summary*
Non-DepMed Use *Details*
Non-DepMed Use *Summary*
Psychotropics *Details*
Psychotropics *Summary*
Surgeon's Recall Roster
Total Utilization By Unit and Name
Select Report Options for Chronic Med Use Summary
Current setting for P-MART reporting dates:
From 28 May 2008 to 29 May 2009
Change Reporting Dates
Select/Deselect Units to Include
High Risk Medication List
Suppress Drugs from Reports
Preview
Print
Report of drug utilization for Chronic Use medications. This is a summary report by drug.
Close This Form
Version 5 • May 2009

Drug Combination Report


P-MART | Prescription Medication Analysis And Reporting Tool - Reports
Select a Report
Chronic Med Use Summary
Chronic Medication Use
Controlled Substance *Details*
Controlled Substance *Summary*
Drug Combination Report
High Risk Medication *Details*
High Risk Medication *Summary*
Mefloquin Combination Patient
Narcotic Medication *Details*
Narcotic Medication *Summary*
Non-DepMed Use *Details*
Non-DepMed Use *Summary*
Psychotropics *Details*
Psychotropics *Summary*
Surgeon's Recall Roster
Total Utilization By Unit and Name
Select Report Options for Drug Combination Report
Select up to three medications from the list below to query the database for patients who have had prescriptions to all the selected medications.
Drug List Search
ACETAMINOPHEN
ACYCLOVIR
ALBUTEROL SULFATE
AMANTADINE HCL
AMLODIPINE BESYLATE
AMOXICILLIN TRIHYDRATE
AZITHROMYCIN
BENZONATATE
Change Reporting Dates
Suppress Drugs from Reports
Reset Selection
Preview
Print
Report show information on all the service members who were prescribed the selected drugs during the given report time frame.
Close This Form
Version 5 • May 2009

User Defined Combination Report

Drug Combination Report

Data current as of 6/5/2009

Date Range: 12/5/2009 - 6/1/2009

Service Members with Prescriptions for ALPRAZOLAM, OXYCODONE HCL, and SIMVASTATIN

SAILOR, NAVY **222222222**

Drug Name:	ALPRAZOLAM 1MG	TABLET		Date Filled:	06 Jan 2009	
Qty:	60	Days Supplied:	30	Pharmacy: RITE AID PHARMACY 07231 #07231 MCCOMB M		Retail
Drug Name:	ALPRAZOLAM 0.5MG	TABLET		Date Filled:	06 May 2009	
Qty:	10	Days Supplied:	10	Pharmacy: WALGREENS DRUG STORE #10835 MCCOMB M		Retail
Drug Name:	OXYCODONE HCL 20MG	TAB,SR 12H		Date Filled:	14 May 2009	
Qty:	15	Days Supplied:	8	Pharmacy: RUCKER MAIN PHCY FT RUCKER AL		MTF

Narcotic “By Drug” Detail Report

Narcotic Medication Report

Data current as of 6/8/2009

Personal Data - Privacy Act of 1974 (PL 93-579)

HYDROCODONE BIT/ACETAMINOPHEN

CENTCOM ☑ *HYDROCODONE-ACETAMINOPH*

				Qty	DS
SAILOR, NAVY	222-22-2222	GUIDEPOINT PHARMACY #102 ROCHESTER MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500MG TABL		03 Apr 2009		120	30
SHIP, GUNNER	666-66-6666	WALGREEN DRUG STORE #10501 VIRGINIA MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500MG TABL		28 Oct 2008		30	5
SOLDIER, ARMY	111-11-1111	DULUTH CLINIC-PHARMACY DULUTH MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 10MG-500MG TABL		20 Aug 2008		18	3
SOLDIER, ARMY	111-11-1111	WALGREEN DRUG STORE #3064 SUPERIOR WI	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 10MG-500MG TABL		23 Oct 2008		30	8
SOLDIER, ARMY	111-11-1111	DULUTH CLINIC-PHARMACY DULUTH MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500MG TABL		07 Nov 2008		40	5
SOLDIER, ARMY	111-11-1111	DULUTH CLINIC-PHARMACY DULUTH MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500MG TABL		12 Nov 2008		40	5
SOLDIER, ARMY	111-11-1111	DULUTH CLINIC-PHARMACY DULUTH MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500MG TABL		26 Nov 2008		28	4
WOUNDED, WARRIOR	555-55-5555	WALGREENS DRUG STORE #11125 HIBBING MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 7.5-500MG TABLET		15 Aug 2008		16	2
WOUNDED, WARRIOR	555-55-5555	WALGREENS DRUG STORE #11125 HIBBING MN	Retail		
HYDROCODONE BIT/ACETAMINOPHEN 7.5-500MG TABLET		20 Aug 2008		16	2

MORPHINE SULFATE

CENTCOM ☑ *MORPHINE SULFATE*

				Qty	DS
SAILOR, NAVY	222-22-2222	GUIDEPOINT PHARMACY #102 ROCHESTER MN	Retail		
MORPHINE SULFATE 30MG TABLET SA		13 Apr 2009		20	10

OXYCODONE HCL

CENTCOM ☐ *OXYCODONE HCL*

				Qty	DS
SAILOR, NAVY	222-22-2222	KASSON DRUG STORE KASSON MN	Retail		
OXYCODONE HCL 5MG TABLET		03 Jun 2008		40	20
SAILOR, NAVY	222-22-2222	KASSON DRUG STORE KASSON MN	Retail		
OXYCODONE HCL 5MG TABLET		23 Jun 2008		40	20

Narcotic “By Drug” Summary Report

Narcotic Utilization Summary

Data current as of 6/8/2009

HYDROCODONE BIT/ACETAMINOPHEN

HYDROCODONE BIT/ACETAMINOPHEN 10MG-500MG TABLE	# of Rxs: 2	Unique Pts: 1	CENTCOM ☐
HYDROCODONE BIT/ACETAMINOPHEN 5MG-500MG TABLET	# of Rxs: 5	Unique Pts: 3	CENTCOM ☑
HYDROCODONE BIT/ACETAMINOPHEN 7.5-500MG TABLET	# of Rxs: 2	Unique Pts: 1	CENTCOM ☐

MORPHINE SULFATE

MORPHINE SULFATE 30MG TABLET SA	# of Rxs: 1	Unique Pts: 1	CENTCOM ☑

OXYCODONE HCL

OXYCODONE HCL 5MG TABLET	# of Rxs: 6	Unique Pts: 1	CENTCOM ☐

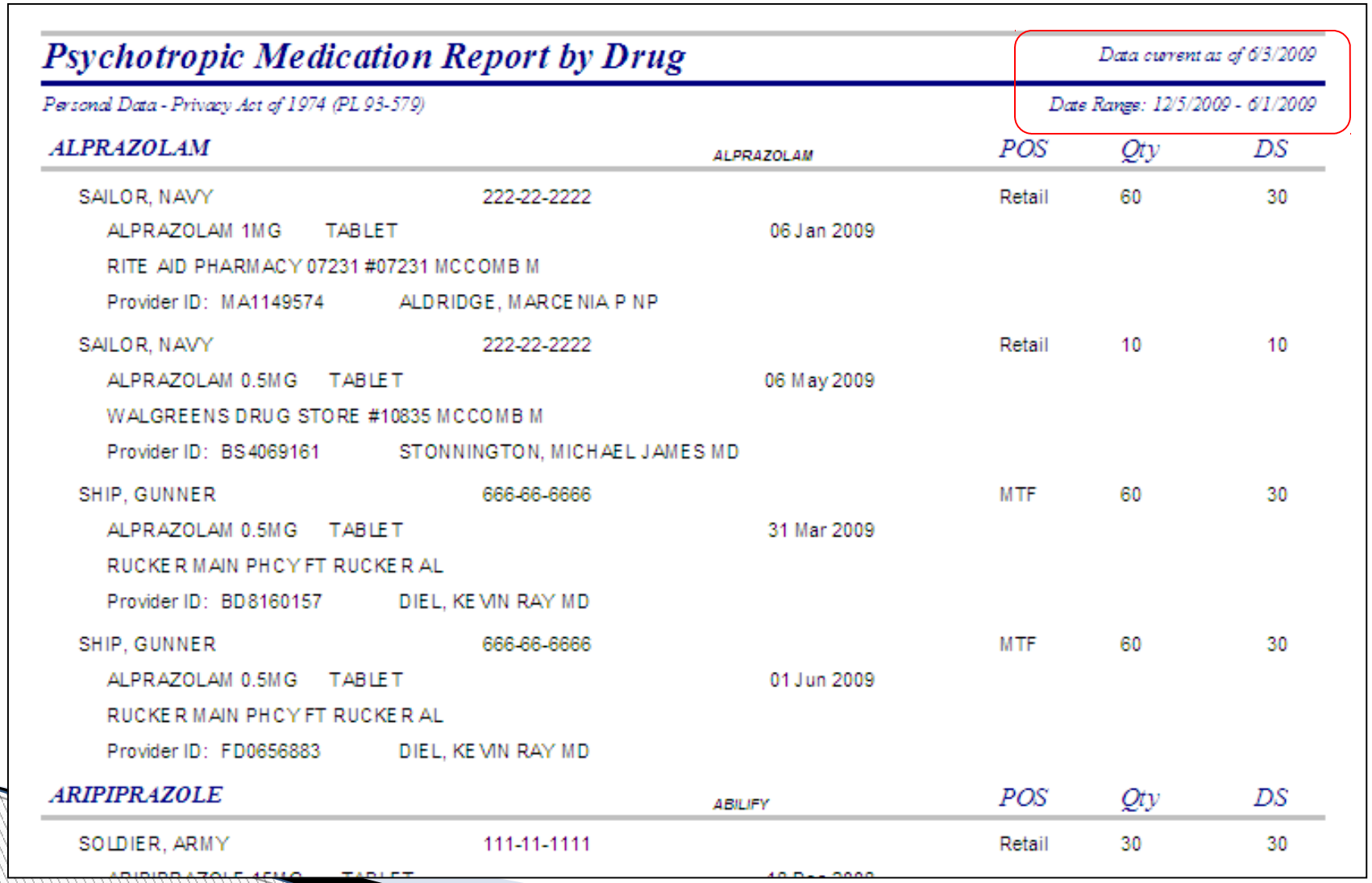
OXYCODONE HCL/ACETAMINOPHEN

OXYCODONE HCL/ACETAMINOPHEN 5MG-325MG TABLET	# of Rxs: 2	Unique Pts: 2	CENTCOM ☑

TRAMADOL HCL

TRAMADOL HCL 50MG TABLET	# of Rxs: 7	Unique Pts: 3	CENTCOM ☑

Psychotropic "By Drug" Detail Report



Psychotropic Medication Report by Drug

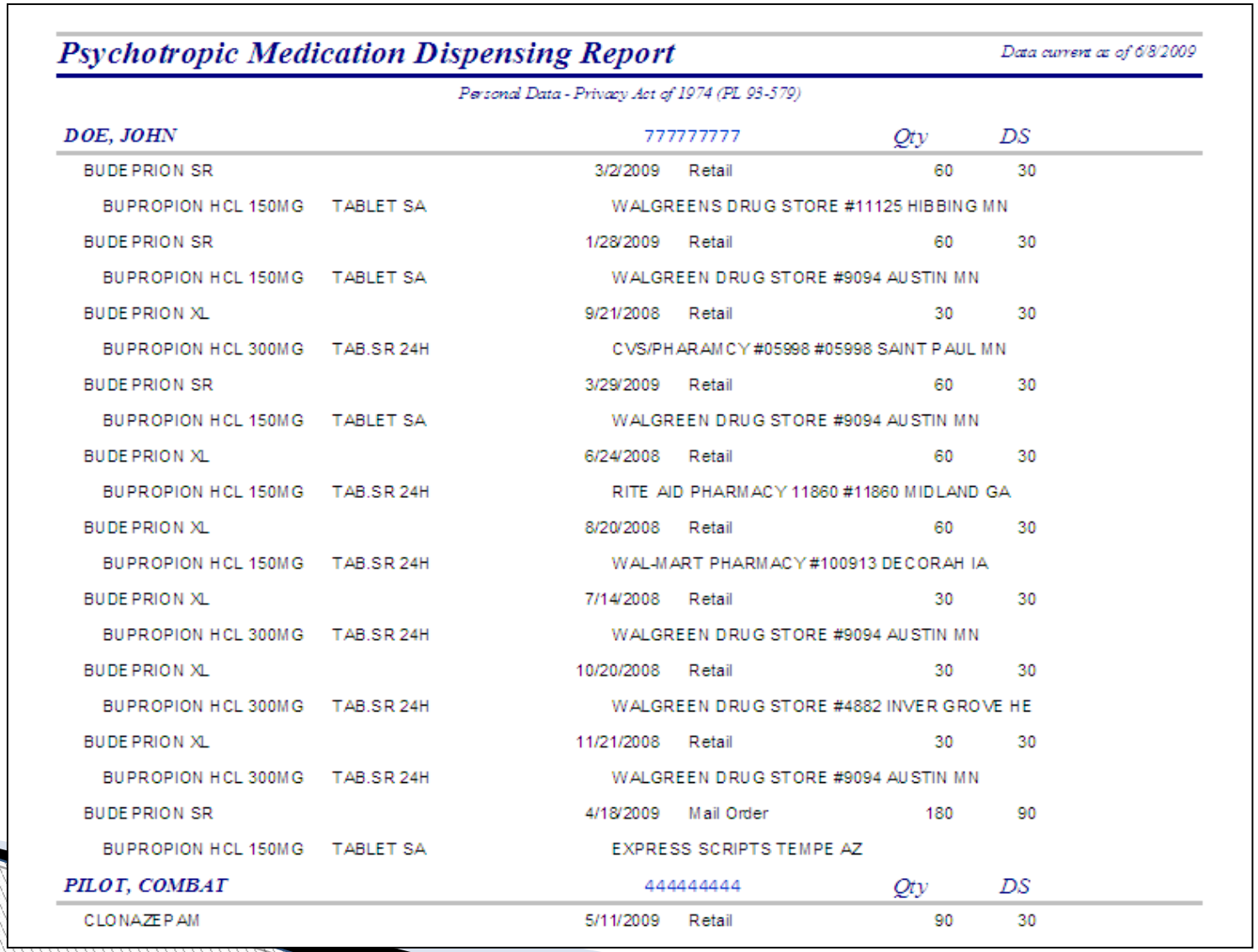
Data current as of 6/3/2009

Personal Data - Privacy Act of 1974 (PL 93-579)

Date Range: 12/5/2009 - 6/1/2009

ALPRAZOLAM	*ALPRAZOLAM*	*POS*	*Qty*	*DS*
SAILOR, NAVY	222-22-2222	Retail	60	30
ALPRAZOLAM 1MG TABLET	06 Jan 2009			
RITE AID PHARMACY 07231 #07231 MCCOMB M				
Provider ID: MA1149574	ALDRIDGE, MARCENIA P NP			
SAILOR, NAVY	222-22-2222	Retail	10	10
ALPRAZOLAM 0.5MG TABLET	06 May 2009			
WALGREENS DRUG STORE #10835 MCCOMB M				
Provider ID: BS4069161	STONNINGTON, MICHAEL JAMES MD			
SHIP, GUNNER	666-66-6666	MTF	60	30
ALPRAZOLAM 0.5MG TABLET	31 Mar 2009			
RUCKER MAIN PHCY FT RUCKER AL				
Provider ID: BD8160157	DIEL, KEVIN RAY MD			
SHIP, GUNNER	666-66-6666	MTF	60	30
ALPRAZOLAM 0.5MG TABLET	01 Jun 2009			
RUCKER MAIN PHCY FT RUCKER AL				
Provider ID: FD0656883	DIEL, KEVIN RAY MD			
ARIPIPRAZOLE	*ABILIFY*	*POS*	*Qty*	*DS*
SOLDIER, ARMY	111-11-1111	Retail	30	30

Psychotropic “By SM” Detail Report

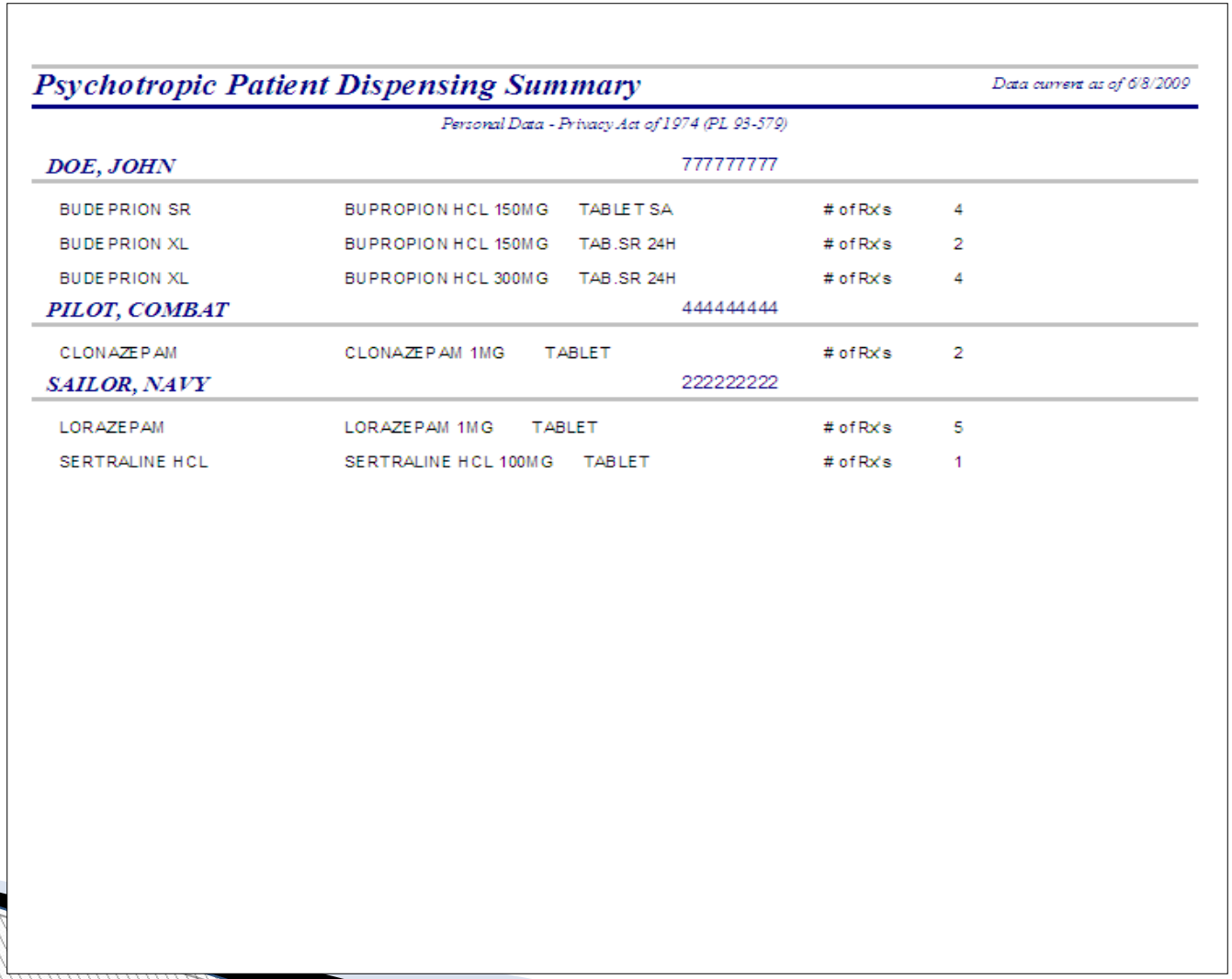


Psychotropic Medication Dispensing Report *Data current as of 6/8/2009*

Personal Data - Privacy Act of 1974 (PL 93-579)

DOE, JOHN		777777777		***Qty***	***DS***
BUDEPRION SR		3/2/2009	Retail	60	30
BUPROPION HCL 150MG	TABLET SA	WALGREENS DRUG STORE #11125 HIBBING MN			
BUDEPRION SR		1/28/2009	Retail	60	30
BUPROPION HCL 150MG	TABLET SA	WALGREEN DRUG STORE #9094 AUSTIN MN			
BUDEPRION XL		9/21/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	CVS/PHARAMCY #05998 #05998 SAINT PAUL MN			
BUDEPRION SR		3/29/2009	Retail	60	30
BUPROPION HCL 150MG	TABLET SA	WALGREEN DRUG STORE #9094 AUSTIN MN			
BUDEPRION XL		6/24/2008	Retail	60	30
BUPROPION HCL 150MG	TAB.SR 24H	RITE AID PHARMACY 11860 #11860 MIDLAND GA			
BUDEPRION XL		8/20/2008	Retail	60	30
BUPROPION HCL 150MG	TAB.SR 24H	WAL-MART PHARMACY #100913 DECORAH IA			
BUDEPRION XL		7/14/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	WALGREEN DRUG STORE #9094 AUSTIN MN			
BUDEPRION XL		10/20/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	WALGREEN DRUG STORE #4882 INVER GROVE HE			
BUDEPRION XL		11/21/2008	Retail	30	30
BUPROPION HCL 300MG	TAB.SR 24H	WALGREEN DRUG STORE #9094 AUSTIN MN			
BUDEPRION SR		4/18/2009	Mail Order	180	90
BUPROPION HCL 150MG	TABLET SA	EXPRESS SCRIPTS TEMPE AZ			
PILOT, COMBAT		444444444		***Qty***	***DS***
CLONAZEPAM		5/11/2009	Retail	90	30

Psychotropic “By SM” Dispensing Summary Report



Psychotropic Patient Dispensing Summary *Data current as of 6/8/2009*

Personal Data - Privacy Act of 1974 (PL 93-579)

DOE, JOHN		777777777		
BUDEPRION SR	BUPROPION HCL 150MG	TABLET SA	# of Rx's	4
BUDEPRION XL	BUPROPION HCL 150MG	TAB.SR 24H	# of Rx's	2
BUDEPRION XL	BUPROPION HCL 300MG	TAB.SR 24H	# of Rx's	4
PILOT, COMBAT		444444444		
CLONAZEPAM	CLONAZEPAM 1MG	TABLET	# of Rx's	2
SAILOR, NAVY		222222222		
LORAZEPAM	LORAZEPAM 1MG	TABLET	# of Rx's	5
SERTRALINE HCL	SERTRALINE HCL 100MG	TABLET	# of Rx's	1

Psychotropic "By Drug" Summary Report

Psychotropic Medication Utilization Summary

Data current as of 6/3/2009

Personal Data - Privacy Act of 1974 (PL 93-579)

Date Range: 12/5/2009 - 6/1/2009

ALPRAZOLAM

ALPRAZOLAM 0.5MG	TABLET	# of Rxs: 3	Unique Pts: 2
ALPRAZOLAM 1MG	TABLET	# of Rxs: 1	Unique Pts: 1

ARIPIPRAZOLE

ARIPIPRAZOLE 15MG	TABLET	# of Rxs: 5	Unique Pts: 1

BUPROPION HCL

BUPROPION HCL 150MG	TABLET SA	# of Rxs: 2	Unique Pts: 1

CITALOPRAM HYDROBROMIDE

CITALOPRAM HYDROBROMIDE 20MG	TABLET	# of Rxs: 5	Unique Pts: 1

CLONAZEPAM

CLONAZEPAM 0.5MG	TABLET	# of Rxs: 3	Unique Pts: 1

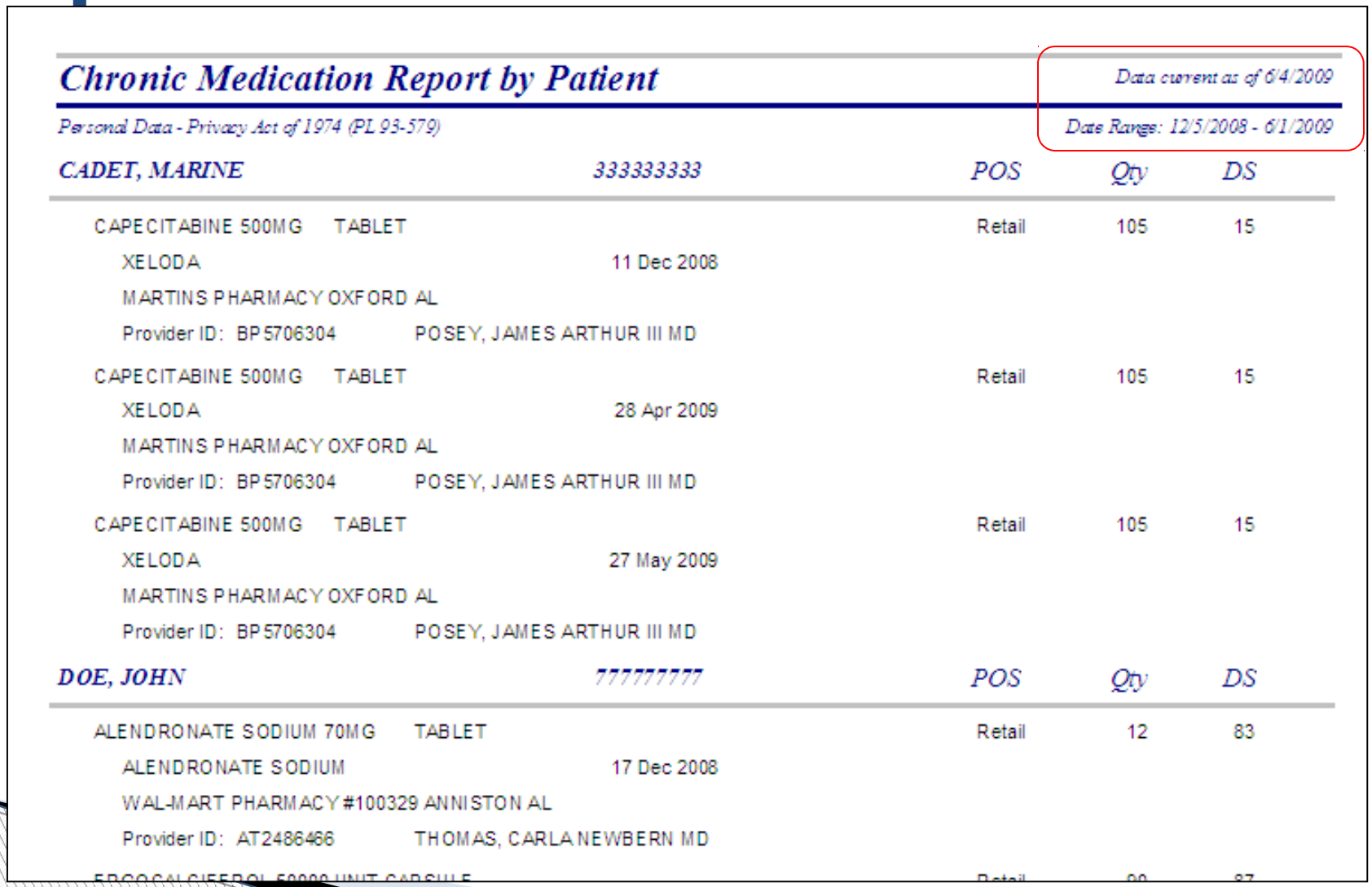
DIVALPROEX SODIUM

DIVALPROEX SODIUM 250MG	TAB.SR 24H	# of Rxs: 6	Unique Pts: 1
DIVALPROEX SODIUM 500MG	TAB.SR 24H	# of Rxs: 6	Unique Pts: 1

ESCITALOPRAM OXALATE

ESCITALOPRAM OXALATE 10MG	TABLET	# of Rxs: 1	Unique Pts: 1

Chronic Medication "By SM" Report



Chronic Medication Report by Patient

Data current as of 6/4/2009

Personal Data - Privacy Act of 1974 (PL 93-579)

Date Range: 12/5/2008 - 6/1/2009

CADET, MARINE	*333333333*	*POS*	*Qty*	*DS*
CAPECITABINE 500MG TABLET		Retail	105	15
XELODA	11 Dec 2008			
MARTINS PHARMACY OXFORD AL				
Provider ID: BP5706304	POSEY, JAMES ARTHUR III MD			
CAPECITABINE 500MG TABLET		Retail	105	15
XELODA	28 Apr 2009			
MARTINS PHARMACY OXFORD AL				
Provider ID: BP5706304	POSEY, JAMES ARTHUR III MD			
CAPECITABINE 500MG TABLET		Retail	105	15
XELODA	27 May 2009			
MARTINS PHARMACY OXFORD AL				
Provider ID: BP5706304	POSEY, JAMES ARTHUR III MD			

DOE, JOHN	*777777777*	*POS*	*Qty*	*DS*
ALENDRONATE SODIUM 70MG TABLET		Retail	12	83
ALENDRONATE SODIUM	17 Dec 2008			
WAL-MART PHARMACY #100329 ANNISTON AL				
Provider ID: AT2486466	THOMAS, CARLA NEWBERN MD			

"Unavailable at Mail Order" Report

Service Members with Medications Unavailable at Mail Order *Data current as of 6/8/2009*

Service Member: DOE, JANE ***SSN:*** 888888888

Unavailable Med:	OTC	OXYMETAZOLINE HCL 0.05% SPRAY
Unavailable Med:	OTC	BENZOYL PEROXIDE 5% GEL
Unavailable Med:	OTC	EUCALYPTUS OIL/MENTHOL 7.6MG LOZENGE
Unavailable Med:	OTC	GUAIFENESIN 100MG/5ML LIQUID
Unavailable Med:	OTC	GUAIFENESIN/P-EPHED HCL 1200-120MG TAB.SR 12H
Unavailable Med:	OTC	IBUPROFEN 200MG TABLET
Unavailable Med:	OTC	LANOLIN/MINERAL OIL LOTION
Unavailable Med:	OTC	ACETAMINOPHEN 325MG TABLET
Unavailable Med:	OTC	METHYL SALICYLATE/MENTHOL 15%-10% CREAM(GM)
Unavailable Med:	OTC	PADIMATE O STICK (EA)
Unavailable Med:	OTC	PHENOL/SODIUM PHENOLATE SPRAY
Unavailable Med:	OTC	PHENYLEPHRINE HCL 10MG TABLET
Unavailable Med:	OTC	POLYVINYL ALCOHOL/POVIDONE 1.4-0.6% DROPERETTE
Unavailable Med:	OTC	PSEUDOEPHEDRINE HCL 30MG TABLET
Unavailable Med:	OTC	MEDICAL SUPPLIES BANDAGE

Service Member: SAILOR, NAVY ***SSN:*** 222222222

Unavailable Med:	TEMP SENSITIVE	PROMETHAZINE HCL 25MG SUPP.RECT
Unavailable Med:	OTC	DOCUSATE SODIUM 100MG CAPSULE

"Your PMART Statistics Report"

Medication Use Statistics

Date Range: 5/28/2008 - 5/29/2009

Personal Data - Privacy Act of 1974 (PL 93-579)

Current Number of Service Members :	8	
Current Number of Prescriptions:	129	
Current Number of Service Members with Prescriptions:	8	100.0%

The below statistics are all subject to available filtering. If you have deselected units or changed the reporting date range on the previous window (Details/Admin window), the counts below will report within these restrictions. The percentages below use Current Number of Service Members/Prescriptions as the denominator.

	Number of Rxs		Number of SMs on at least one:	
High Risk Medications:	25	19.4%	4	50.0%
Non-Deployment Medications:	60	46.5%	8	100.0%
Chronic Medications:	59	45.7%	8	100.0%
Controlled Medications:	25	19.4%	6	75.0%
Narcotic Medications:	25	19.4%	5	62.5%

PMART Facts and Findings

- 700 PMART/WTU reports completed resulting in 8.4 million reviewable prescriptions for 1.8 million service members
- Completed 479 Army, 154 Navy, 37 Air Force, 29 Marine, & 1 Coast Guard PMART/WTU reports
- Identified 408,658 (23%) service members who were taking high-risk medications

Current as of 31 May 11

How To Order PMART Report?

- Contact PEC at DSN 471-8274 COMM 210-221-8274 or email p-mart@amedd.army.mil
- Provide Unit Alpha Roster via PEC Secure Server
- Complete Sensitive Data Request Form
- Located at:

www.pec.ha.osd.mil/pmart

Sensitive Data Request Form

DOCUMENT INFORMATION	**Original Author:**	Hector Morales, Director TMA Pharmacy Operations Center
	Date:	August 2011

P-MART TYPE	☐ P-MART ☐ WTU P-MART	
Date of Request		
Date Required		(3-5 Business Day Turn-Around)
Requestor	Name: Phone Number: MTF Installation: Title: Email:	
Signature		

PMART Summary

- PMART is a tool to assist in the pre-deployment medical screening process
- Fast and efficient tool for screening medication use
- Easy to navigate and no additional cost to use
- Specialized to a particular audience, for a specific purpose

Review of February 2012 P&T Committee Meeting

Dave Meade, PharmD, BCPS
Clinical Pharmacist

February 2012
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - ADHD/Wakefulness Promoting Agents
  - Antiplatelet Agent
  - DPP-4 Subclass - Non Insulin Antidiabetic Agents

- **New Drugs in Previously Reviewed Classes**
  - Alcaftadine (Lastacaft) - Ophthalmic
  - Nucynta ER (Tapentadol ER) - Narcotic Analgesics

February 2012
DoD P&T Committee Meeting

- **Utilization Management**
  - Crizotinib (Xalkori)
  - Vermurafenib (Zelboraf)
  - Ivacaftor (Kalydeco)

Uniform Formulary Class Reviews: ADHD/Wakefulness Promoting Agents

Class Definition
ADHD – Wakefulness Promoting

- 3 Subclasses
  - ADHD Stimulants
  - ADHD Non-stimulants
  - Wakefulness Promoting Agents

ADHD Stimulants

ADHD Stimulants
Drugs in the Class

Generic Name	Brand Name	Frequency	Duration, Hrs	FDA Approval	Generic Availability
Mixed amphetamine salts XR	Adderall XR	QD	10	10/11/2001	Authorized generic
Methylphenidate OROS	Concerta	QD	12	12/8/2000	Authorized generic
Lisdexamphetamine	Vyvanse	QD	10-12	12/10/2007	N
Dexmethylphenidate ER	Focalin XR	QD	8-12	8/1/2006	N
Methylphendiate CD	Metadate CD	QD	6-8	2/19/2006	N
Methylphenidate LA	Ritalin LA	QD	6-8	generic	Y
Methylphenidate ER	Metadate ER	QD	8	6/1/1988	N
Methylphenidate ER	Methylin ER	QD	8	5/9/2000	N
Methylphenidate IR	Ritalin	BID-TID	3-5	generic	Y
Dextroamphetamine sulfate	Dexedrine Procentra	BID-TID BID-TID	4-6 3-5	Generic 1/29/2008	Y N
Methylphenidate chewable	Methylin	BID-TID	3-5	12/9/2002	N
Dexmethylphenidate IR	Focalin	BID	3-5	generic	Y
Methylphenidate SR	Ritalin SR	BID	2-6	generic	Y
Methamphetamine HCl	Desoxyn	BID	4-5	generic	Y
Mixed amphetamine salts	Adderall	BID	6	generic	Y
Methylphenidate transdermal	[illegible]ytrana	Apply for 9 hrs	11-12	4/6/2006	N

ADHD Non-stimulants

ADHD Non-Stimulants
Drugs in the Class

Generic Name	Brand Name	Frequency	Duration, Hours	FDA Approval	Generic Availability
Atomoxetine HCL	Strattera	QD-BID	10-12	11/26/2002	N
Clonidine HCL XR	Kapvay	QD-BID	10-12	9/28/2010	N
Guanfacine HCL XR	Intuniv	QD	10-12	9/2/2009	N
Clonidine IR	generic	BID-QID	3-5	generic	Y
Guanfacine IR	generic	BID-TID	4-8	generic	Y

Overall Clinical Effectiveness Conclusion
ADHD Stimulants and Non-stimulants

- **Efficacy**
  - Preschool-aged children (4 -5 years of age):
    - The Preschool ADHD Treatment Study (PATS) showed MPH IR was more effective than placebo in improving ADHD symptoms in preschoolers who still had moderate to severe ADHD symptoms after 10 sessions of Parental Behavioral Training (PBT)
  - Children and Adolescents (6-17 years of age):
    - No clinically relevant difference between IR stimulants
    - No clinically relevant differences between IR vs. SR stimulants
    - No clinically relevant differences between SR vs. SR stimulants, however some SR stimulants showed benefit over comparators at specific times of day depending on the pharmacokinetics of the specific formulation, but overall differences were not found

PH IR: methylphenidate immed release

Overall Clinical Effectiveness Conclusion
ADHD Stimulants and Non-stimulants

- **Efficacy**
  - Children and Adolescents (6-17 years of age):
    - Atomoxetine was not superior to some ER stimulants - MPH OROS (Concerta) and MAS XR (Adderall XR)
    - ER clonidine and ER guanfacine have no comparative efficacy evidence to date. Both are superior to placebo for monotherapy and as adjuncts to stimulants
  - Adults (18 years and older)
    - No clinically relevant differences between switching to MPH OROS vs. continuing with MPH IR

Overall Clinical Effectiveness Conclusion ADHD Stimulants and Non-stimulants

- **Safety**
  - Black box warnings for stimulants (abuse and dependency) and atomoxetine (suicidal ideation)
  - Atomoxetine has increased risk of suicidal behavior compared with placebo (DERP)
  - Atomoxetine resulted in higher rates of vomiting and somnolence, similar rates of nausea and anorexia, and lower rates of insomnia than stimulants (DERP)
  - Stimulants showed no significant increased risk for serious cardiovascular events in children, adolescents, and adults (up to age 64) based on large retrospective, population based cohort study (JAMA and NEJM)
  - The Multimodal Therapy Study of ADHD (MTA) showed a decrease in growth velocity with stimulants at 36 months
  - An uncommon but significant adverse effect of stimulants is the occurrence of hallucinations and other psychotic symptoms in children
  - ER clonidine and ER guanfacine have no comparative safety evidence, however their most common adverse events include somnolence and fatigue

Overall Clinical Effectiveness Conclusion ADHD Stimulants and Non-Stimulants

- **Other Factors:**
  - Evidence on abuse, misuse, and diversion was limited, but indicated that stimulant use during childhood is not associated with increased risk of substance abuse later
  - Misuse and diversion rates varied by age and were highest among college students, and rates of diversion were highest with amphetamine-based products but similar among methylphenidate products
  - AAP ADHD Guidelines recommend prescribing non-stimulants or stimulants with less abuse potential (lisdexamfetamine [Vyvanse], methylphenidate transdermal system [Daytrana], methylphenidate OROS [Concerta] for adolescents due to abuse/diversion concerns (AAP 2011 ADHD Guidelines)
  - One stimulant (lisdexamfetamine) can be dissolved in water, and several other stimulants can be sprinkled on food

AAP: American Academy of Pediat

ADHD Stimulants – Final Decision

BCF	UF	NF
Long-acting stimulants ▪ Mixed amphetamine salts ER (Adderall XR generics) ▪ Methylphenidate LA (Ritalin LA, generic) ▪ Methylphenidate OROS (Concerta) **Short-acting stimulants** ▪ Methylphenidate IR (Ritalin, generic)	**Short-acting stimulants** ▪ Mixed amphetamine salts IR (Adderall, generic) ▪ Dexmethylphenidate IR (Focalin, generic) ▪ Dextroamphetamine (Dexedrine, Dextrostat, Procentra solution) ▪ Methylphenidate CD (Metadate CD) ▪ Methylphenidate ER (Metadate ER, Methylin ER, generic) ▪ Methylphenidate chewable tablets, solution (Methylin, generic) ▪ Methylphenidate SR (Ritalin SR, generic) ▪ Methamphetamine HCl (Desoxyn)	**Long-acting stimulants** ▪ Dexmethylphenidate ER (Focalin XR) ▪ Lisdexamphetamine (Vyvanse) ▪ Methylphenidate transdermal system (Daytrana)

ADHD Non-Stimulants – Final Decision

BCF	UF	NF	Comments
▪ Not applicable	▪ Atomoxetine (Strattera) ▪ Clonidine ER (Kapvay) ▪ Guanfacine ER (Intuniv)	▪ Not applicable (no nonformulary drugs)	Clonidine IR tabs are BCF Clonidine Patches and guanfacine IR (Tenex, generic are UF) in Misc Anti-hypertensive Drug Class

Wakefulness Promoting Agents

Wakefulness Promoting Agents
Drugs in the Class

Generic Name	Brand Name	FDA Approval	Patent Expiration	Generic Availability
Armodafinil	Nuvigil	6/15/2007	2024	No
Modafinil	Provigil	12/24/1998	4/6/2012	April 2012
Sodium Oxybate	Xyrem	7/17/2002	2019-2024	No

Overall Clinical Effectiveness Conclusion Wakefulness-Promoting Agents

- No direct comparison of modafinil and armodafinil for the indications of narcolepsy and OSA
- One head to head trial, comparing modafinil 200mg/day to armodafinil 150mg/day, showed that both drugs have similar efficacy for shift work sleep disorder
- Armodafinil did not receive FDA approval for the indication of jet lag disorder
- No significant differences in safety/tolerability between armodafinil and modafinil

OSA: *obstructive sleep apnea*

Overall Clinical Effectiveness Conclusion Wakefulness-Promoting Agents

- Sodium oxybate (Xyrem) fills a unique niche in therapy for cataplexy associated with narcolepsy
- Sodium oxybate did not receive FDA approval for fibromyalgia due to abuse and safety concerns
- Sodium oxybate (Xyrem) has a black box warning for abuse/misuse/diversion potential and has a restricted distribution system which uses one centralized pharmacy
- Most common adverse events leading to discontinuation of sodium oxybate were headache, nausea, vomiting, and anxiety

Wakefulness Promoting Subclass Prior Authorization Recommendation

- Provigil
  - No change to current PA
- Nuvigil
  - Add Jet Lag disorder to “not covered” off-label use part of PA
  - Trial of Provigil first will be added to PA (“Has the patient tried Provigil – if no, then coverage denied”)
  - Patients would not be grandfathered
- Xyrem
  - Covered for FDA- approved indication of cataplexy associated with narcolepsy diagnosed by polysomnogram and MSLT
  - Should try Provigil prior to using for excessive sleepiness associated with narcolepsy without cataplexy
  - Not covered for any off label uses including fibromyalgia, insomnia, or excessive sleepiness not associated with narcolepsy

Wakefulness Promoting Agents– Final Decision

BCF	UF	NF	Comments
▪ Not applicable	▪ Modafinil (Provigil) ▪ Sodium oxybate (Xyrem) – restricted distribution	▪ Armodafinil (Nuvigil)	▪ All current and new users of Nuvigil must go through PA process

Uniform Formulary Class Reviews: Antiplatelet Agent

Drugs in the Class

Generic name	Brand name	Approval date	Generic availability?
Thienopyridines			
Ticlopidine	Ticlid	October 31, 1991	Yes
Clopidogrel	Plavix	November 17, 1997	No
Prasugrel	Effient	July 10, 2009	No
Cyclopentyltriazolopyrimidines			
Ticagrelor	Brilinta	July 20, 2011	No
Phosphodiesterse inhibitors			
Dipyridamole	Persantine	December 6, 1961	Yes
Aspirin/ER dipyridamole	Aggrenox	November 22, 1999	No
Cilostazol	Pletal	January 15, 1999	Yes
Hemorrheologic Agent - Blood Viscosity Reducer Agent			
Pentoxifylline	Trental, Pentopak, Pentoxil	August 30, 1984	Yes

Overall Clinical Effectiveness Conclusion

- **Efficacy**
  - ACS
    - Prasugrel and ticagrelor are less susceptible to genetic variation and drug-drug interactions with PPI, have faster onset of action and exhibit more complete platelet inhibition compared to clopidogrel
    - Prasugrel decreases major coronary events including non-fatal MI and stent thrombosis in ACS patients undergoing PCI, when compared with clopidogrel therapy
    - Prasugrel only approved for ACS patients suitable for PCI
    - Ticagrelor decreases major coronary events including non-fatal MI and stent thrombosis, when compared with clopidogrel therapy
      - US patients; no significant difference in the rate of primary outcome between the two groups (10.1% vs 12.6%, p=0.1459) (attributed to high aspirin dose)

Overall Clinical Effectiveness Conclusion

- **Efficacy**
  - Stroke/TIA
    - No significant difference between Aggrenox and clopidogrel for all-cause mortality, CV mortality, and recurrent stroke
    - No significant difference between clopidogrel and ticlopidine in reduction of all-cause mortality, CV death, or cerebral infarction
  - Peripheral artery disease (PAD)
    - Cilostazol is the first-line agent to improve walking distance while pentoxifylline is the second-line alternative
    - Clopidogrel and aspirin are recommended to reduce the risk of MI, stroke or vascular death in patients with symptomatic PAD

TIA: Transient Ischemic

Overall Clinical Effectiveness Conclusion

- **Safety and Tolerability**
  - Prasugrel is associated with significant increase in bleeding vs. clopidogrel
    - Increased risk in low-weight, elderly patients
    - Avoid use around CABG or other surgical or invasive procedures
  - Ticagrelor: rate of major bleeding, life-threatening or CABG-related major bleeding was similar to clopidogrel
    - Ticagrelor had a higher rate of non-CABG major bleeding
    - More episodes of dyspnea in the ticagrelor group and more d/c due to this adverse effect
  - Unlike clopidogrel and ticagrelor, prasugrel is contraindicated in patients with previous stroke or TIA
  - Ticlopidine's therapeutic use limited by neutropenia/agranulocytosis, TTP and aplastic anemia
  - Clopidogrel had lower rate of major bleeding and withdrawal due to AEs compared with ER dipyridamole/aspirin

TP: Thrombotic Thrombocytopenic [illegible]pura

Antiplatelet Agent– Final Decision

BCF	UF	NF
▪ Clopidogrel (Plavix)	▪ Prasugrel (Effient) ▪ Ticagrelor (Brilinta) ▪ Aspirin/dipyridamole ER (Aggrenox) ▪ Ticlopidine (Ticlid, generics) ▪ Cilostazol (Pletal), generics) ▪ Dipyridamole (Persantine, generics) ▪ Pentoxifylline (Trental, generics)	▪ No drug designated nonformulary

Clopidogrel generics are now available (May 2012)

Uniform Formulary Class Reviews:
DPP-4 Subclass -
Non Insulin Antidiabetic Agents

Drugs in the Class

Active Ingredient	Brand (Manufacturer)	Strengths
Sitagliptin	Januvia (Merck)	25mg, 50mg, 100mg
Sitagliptin/ Metformin	Janumet (Merck)	50mg/500mg, 50mg/1000mg
Sitagliptin/ Metformin ER	Janumet XR (Merck)	50mg/500mg, 50mg/1000mg, 100mg/1000mg
Sitagliptin/ Simvastatin	Juvisync (Merck)	100mg/10mg, 100mg/20mg, 100mg/40mg
Saxagliptin	Onglyza (BMS)	2.5mg, 5mg
Saxagliptin/ Metformin ER	Kombiglyze XR (BMS)	2.5mg/1000mg, 5mg/500mg, 5mg/1000 mg
Linagliptin	Tradjenta (Boehringer Ingelheim)	5mg
Linagliptin/ Metformin	Jentadueto (Boehringer Ingelheim)	2.5/500mg, 2.5mg/850mg, 2.5mg/1000mg

Overall Clinical Effectiveness Conclusion

- **Efficacy**
  - All 3 agents have similar A1c lowering effect when used as monotherapy ~0.4-0.9%
  - Combined with metformin, mean □ A1c is 0.4-2.5%
  - Combined with TZD mean □ A1c is 0.7-1.06%
  - Combined with SU the mean □ A1c is 0.5-0.6%
  - SIT fixed dose combination with metformin provides a □ A1c of 1.9% from baseline
  - One head-to-head trial did not show clinically significant differences in efficacy or safety between SIT and SAX
  - DPP-4 inhibitors are weight neutral, lipid neutral, and have minimal impact on blood pressure
  - Juvisync is a combination drug that may benefit patients requiring both sitagliptin and a statin

: sitagliptin; SAX: saxagliptin; TZD: [illegible]zolidinedione; SU: sulphonylurea

Overall Clinical Effectiveness Conclusion

- **Safety and Tolerability**
  - DPP-4 inhibitors are generally well-tolerated with few side effects and few drug interactions
  - Pancreatitis has been reported with sitagliptin and saxagliptin
  - Acute renal failure has been reported with sitagliptin
  - Linagliptin is the only DPP-4 inhibitor that does not require dose adjustments

DPP-4 Subclass– Final Decision

BCF	UF	NF	Comments
▪ Sitagliptin (Januvia) ▪ Sitagliptin/Metformin (Janumet)	▪ Sitagliptin/Simvastatin (Juvisync) ▪ Linagliptin (Tradjenta)	▪ Saxagliptin (Onglyza) ▪ Saxagliptin/Metformin ER (Kombiglyze XR)	Must try metformin and sulfonylurea 1st before any DPP-4 drug Must try sitagliptin-containing product 1st before Onglyza, Kombiglyze XR, and Tradjenta

DM Drugs Step Therapy Defined

- Metformin/Sulfonylurea step
  - Applies to DPP-4s, GLP-1s, TZDs
  - Initially implemented in Nov 2010
- DPP-4s
  - Step therapy for the class
    - Januvia, Janumet step-preferred
    - Tradjenta – behind step, but UF
    - Onglyza, Kombiglyze XR – behind step and NF
- New User: A patient who has been prescribed a

  Non-Preferred agent but has not tried the Non-Preferred agent
- Metformin/SU trial required when switching between classes, but not within subclasses

GLP-1: glucagon- like peptide-1

DM Step Therapy Set Up

Subclasses	Prescribed Medication	Step 1 Look Back (180 days)	Message to Pharmacy
DPP-4	Januvia Janumet Janumet XR Juvisync	Metformin or Sulfonylurea	Must try Metformin or a Sulfonylurea first
	Onglyza Kombiglyze XR Tradjenta Jentadueto	Metformin or Sulfonylureas or DPP-4	Must try Januvia/Janumet /Juvisync first and have a history of metformin or a sulfonylurea
TZD	Actos	Metformin or Sulfonylureas	Must try Metformin or a Sulfonylurea first
GLP-1	Byetta	Metformin or Sulfonylureas or GLP-1	Must try Metformin or a Sulfonylurea first
	Victoza		Must try Metformin or a Sulfonylurea and a trial of Byetta

New Drugs in Previously Reviewed Classes

Alcaftadine ophthalmic solution (Lastacaft)

Ophthalmic 1 - Drugs in the Class

Generic Name	Brand	Strength	Generic	FDA Approval
Antihistamines				
Emedastine	Emadine	0.05%	No	1997
Mast Cell Stabilizers				
Pemirolast	Alamast	0.01%	No	1999
Nedocromil	Alocril	2%	No	1999
Cromolyn	Crolom/ Opticrom	4%	Yes	1995/1984
Lodoxamide	Alomide	0.1%	No	1993
Dual Action Antihistamines/Mast Cell Stabilizers				
Alcaftadine	Lastacaft	0.25%	No	2010
Ketotifen	Zaditor	0.025%	Yes OTC	1999
Bepotastine	Bepreve	1.5%	No	2009
Olopatadine	Patanol	0.1%	No	1996
	Pataday	0.2%	No	2004
Azelastine	Optivar	0.05%	Yes	2000
Epinastine	Elestat	0.05%	No	2003

Alcaftadine ophthalmic solution

- Background
  - H1 histamine receptor antagonist
  - Inhibits release of histamine from mast cells
  - 0.25% solution
- Indication
  - Prevention of itching associated with allergic conjunctivitis (AC)
- Potential Off Label Uses
  - Non-ocular symptom relief
    - Rhinorrhea
    - Nasal pruritus
    - Nasal congestion
    - Ear and/or palate pruritus

Overall Clinical Effectiveness Conclusion

- **Efficacy**
  - Alcaftadine provides a once daily option for the prevention of symptoms associated with AC
  - Superiority over placebo was demonstrated in 3 clinical trials
  - Alcaftadine was effective in the prevention of ocular itching 3, 5, and 7 minutes after allergen challenge, and conjunctival redness, 7, 15, and 20 minutes after allergen challenge at Visits 3 and 4 based on statistically significant differences compared with vehicle
  - A clinically relevant difference (at least 1-unit difference in mean score) was also seen in ocular itching at all post-challenge evaluations at Visit 3 and Visit 4. The difference in conjunctival redness between the treatment groups, however, did not reach the criteria for clinical relevance
- **Safety**
  - Most common adverse events included eye irritation, pruritis, and redness, and instillation site burning and stinging
  - In the absence of direct comparative trials between alcaftadine and other dual action AH/MCSs, there is insufficient evidence to suggest clinically relevant differences in efficacy or safety between the agents

Tapentadol Extended Release (Nucynta ER)

Nucynta ER

- Background
  - Tapentadol (Nucynta ER) is a twice daily mu-agonist and norepinephrine reuptake inhibitor analgesic
  - Scheduled II narcotic
- Indications
  - Relief of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time
- Dosage and Administration
  - Available in 50, 100, 150, 200, and 250mg tablets
  - Opioid naïve and experienced: Initial dose of 50mg twice daily (approx. 12 hours apart) with titration in 50mg increments every 3 days as needed to reach effective dose of 100-250mg twice daily (max daily dose 500mg)

Overall Clinical Effectiveness Conclusion

- Two indirect comparisons in CLBP and OA show no clinically relevant differences b/w tapentadol ER and oxycodone CR in terms of pain control, but there was a high drop-out rate in the Oxy CR group
- Overall, clinical evidence is limited
  - No head-to-head comparisons with other opioids
- Nucynta ER in one-52 week trial showed a lower rate of GI effects, but higher incidence of CNS effects compared with oxycodone CR
- It is unknown whether NE reuptake inhibition is an advantage or disadvantage

CLBP- Chronic Lower Back Pain Osteoarthritis GI- Gastrointestinal NE-

New Drugs in a Previously Reviewed Class
Final Decisions

Drug	BCF	UF	NF
• Ophthalmic-1		•Alcafatinde 0.25% (Lastacaft)	
• Narcotic Analgesics		• Tapentadol ER (Nucynta ER)	

Utilization Management

Drugs with genetic testing

- Type of Drug:
  - Crizotinib (Xalkori) is an anaplastic lymphoma kinase (ALK) inhibitor
    - Treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is ALK-positive as detected by an FDA-approved test
  - Vermurafenib (Zelboraf) is an oral Kinase inhibitor
    - Treatment of patients with unresectable or metastatic melanoma with $BRAF^{v600E}$ mutation as detected by an FDA-approved test
    - Not recommended for use in patients with wild-type BRAF melanoma
  - Ivacaftor (Kalydeco)
    - Treatment of CF in patients 6 yrs and older who have a G551D mutation in the CFTR gene (4% of CF patients)
    - Not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene (~90% of CF patients)

Review of May 2012 P&T Committee Meeting

Dave Meade, PharmD, BCPS
Clinical Pharmacist

May 2012
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Smoking Cessation Program
  - Newer Sedative/Hypnotics Drug Class

- **New Drugs in Previously Reviewed Classes**
  - Gabapentin enacarbil (Horizant)
  - Gabapentin ER (Gralise)

RAA: renin-angiotensin-aldosterone

Questions?

Webcast Evaluations

- Please assist us in improving the webcast presentations by completing an anonymous, 5-question survey
- Link: http://www.zoomerang.com/Survey/WEB22CTVSNWFRP
- Thank you!

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